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L7: Entry 44 of 66

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TITLE: Method of disease treatment utilizing an immunologically whey fraction

BSPR:

As is common with most domestic animals, bovine calves are born without immunity. Passive immunity is transferred on a postpartum basis from a dam (mother) to the newborn calf through an initial mammary gland secretion known as colostrum. This initial colostrum secretion contains rapidly diminishing levels of immunologically active, large molecular weight proteins known as immunoglobulins (abbreviated below as "Ig"). These Ig molecules possess antibody properties, are actively produced by mature animals, and enhance immunity to infection by bacteria, viruses or parasites. At birth, a calf lacks Ig in its blood serum. Only as a direct response to ingestion and absorption of a quantity and quality of Ig from maternal colostrum shortly after birth can a calf's immune system function efficiently.

BSPR:

To combat the immunity deficiency problems outlined above, some dairymen having small dairy herds manually milk what they believe to be an adequate quantity of colostrum from a dam and force feed it to its newborn calf during the critical absorption period. This labor intensive method of controlling the timing and quantity of colostrum consumption cannot compensate for colostrum having a low Ig concentration or an inadequate spectrum of pathogen specific antibodies. Since only complex, time consuming laboratory tests can measure the colostrum Ig concentration and antibody distribution, these dairymen have no way of verifying that the colostrum which they laboriously obtain and force feed to newborn calves will provide adequate levels of passive immunity.

DEPR:

A test, known as the "EIA" test, measures the activity of pathogen specific antibodies in the filtered product and is described in an article entitled "Quantification of Bovine IgG, IgM and IgA Antibodies To Clostridium Perfringens B-Toxin By Enzyme Immunoassay I. Preparturient Immunization For Enhancement Of Passive Transfer of Immunity." This article was published in Veterinary Immunology and Immunopathology, Vol. 4 (1983) at pp. 579-591 and was authored by W. A. Fleenor and G. H. Stott. The disclosure of that article is hereby incorporated by reference. The EIA test procedure discussed in that article is known to persons of ordinary skill in the appropriate field.

DEPR:

The passive immunity transfer mechanism implemented according to the present invention has been discussed primarily in connection with dairy cattle. However, beef cattle and other non-bovine domestic animals that achieve passive immunity to disease in response to ingestion of a colostrum-like mammary gland secretion can also benefit from implementation of the process of the present invention. Dairy cattle have been focussed upon primarily due to the recognized and publicized immunity problems encountered and the resulting highly adverse economic impact on dairymen.

DEPR:

A recently published research study suggests the possibility that bovine antibodies such as the anti-rotavirus antibody may possess sufficient activity against human rotavirus strains to provide protection against symptomatic infection. If further investigation establishes that bovine antibodies do in fact combat selected human diseases, the immunologically active filtered product of the present invention could be used to provide protection against those diseases in humans.

DEPR:

It is clear that the whey-derived product of the invention could readily function as a supplement for natural colostrum to either boost the effective level of Ig in natural colostrum having an insufficient level of Ig or to serve as a source of broad spectrum active immunity ultimately achieved by the immune system of a calf or other bovine. The whey-derived product could also be used on a continuous basis as a food supplement for a calf, a mature cow or any other animal including humans to enable the immunologically active immunoglobulin and other immunologically active whey components in the product to attack pathogens present in the animal digestive system. Comparatively low levels of the product could be used when it functions as a food supplement, potentially on the order of approximately two grams or less per day per hundred pounds of animal weight.

DEPR:

The immunologically active filtered product of the present invention can be used in many different applications. One specific application of the filtered product has been extensively described in connection with the transfer of passive immunity to neonate calves. Since pigs, goats, sheep and other domestic animals possess similar immunity transfer mechanisms, the filtered product may be used to transfer passive immunity to all such animals. In view of the fact that bovine antibodies have been demonstrated to be effective to counteract human antigens, the filtered product can be used in a disease resisting application to combat human diseases or to reduce the susceptibility of humans to selected diseases. The incorporation of a defined dosage of the filtered product into infant formula to increase the capability of an infant to resist disease represents a preferred human application of the filtered product. The filtered product may also be used as a feed supplement for either immature or adult domestic animals or as a food supplement

for either immature or adult humans. The filtered product may t also be used to modify the colon or intestinal bacteria colonization or to control or reduce oral microbial colonization for the purpose of controlling the formation of oral plaque. Numerous other uses and applications of the filtered product of the present invention will be readily apparent to a person of ordinary skill in the veterinary, medical and immunology fields.

DEPU:

7. Infectious Bovine Rhinotracheitis; and